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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,793	10/25/2001	Euljoon Park	99P1028US01	7924

7590 05/04/2004

PACESETTER, INC.
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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,793

Applicant(s)

PARK ET AL.

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-19 is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Applicant is advised that the Notice of Allowance mailed October 16, 2003 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt (Pat. No. 5,354,317).

Alt discloses in Figures 1, 3, 4, and 6-8 an implantable cardiac stimulation device (10; col. 6, l. 15) comprising: a sensor (12; col. 6, l. 24) that monitors an indicator of patient activity level (col. 7, l. 2-3, "activity/position sensor"); a pulse generator (19; col. 6, l. 21) that generates stimulation pulses (col. 6, l. 21-23); and circuitry (20,22; col. 6, l. 23, 29) connected to the sensor and the pulse generator (see Fig. 1), the circuitry being operative to process the signals from the sensor (col. 6, l. 23-30) and being responsive to a predetermined change in patient activity level to implement an orthostatic therapy (col. 9, l. 23-50), the circuitry being operative to control the pulse generator based on the orthostatic compensation therapy (Fig. 9; col. 9, l. 51-57).

4. For completeness of record and to reflect how the claim language has been construed by the Office in light of the Alt reference, it is considered helpful to address certain issues associated with the Alt reference such that one reading the prior art

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document will better understand the Office's position and know that such issues were considered but deemed insufficient to support patentability.

5. While the following points could be made by the applicant in an attempt to support a claim for patentability:

(A). The essential difference between the Alt device and the claimed invention of Euljoon et al. is that the device of Alt implements orthostatic compensation therapy (OCT) responsive to predetermined changes in posture, or more accurately to predetermined changes in orientation of the accelerometer with respect to a gravitational field (col. 7, lines 42-62), while the device of Euljoon et al. implements OCT responsive to predetermined changes in activity level, and that a circuit responsive to accelerometer orientation is not the same as a circuit responsive to predetermined changes in patient activity;

(B). While a change in activity level *may* be occurring (a change in activity level is not inherent with a change in position such as where a subject might be riding a rollercoaster or in a car, changing position with respect to gravity, but remaining seated and inactive) during the transition period when a patient rises from a prone or supine position to a standing position, the device of Alt is not designed to measure any change in activity level occurring during the transition from one posture state to the other and implement OCT in response to a measured and predetermined change in this quantity; The device of Alt monitors for discrete *static* values representative of the orientation of the accelerometer with respect to gravity (see col. 7, lines 63-65); The activity level for standing in a non-moving stable position is the same as the activity level for sitting or lying down in a non-moving stable position; There is therefore no change in activity level between the static state of lying down and the static state of standing upright --only possibly a change in activity during the transition period while moving between the two static states; Since Alt has not designed his device to monitor the transition period between static states, it cannot possibly monitor a "predetermined change in activity level" to implement OCT responsive thereto; The device of Alt is not capable of distinguishing between sitting down and standing up since both positions result in the same static output from the accelerator (i.e., 1g) and since Alt does not detect for a

predetermined change in activity level; The applicants' invention to the contrary can detect the difference between sitting and standing (note the first paragraph of page 4 of the present specification) since it does not rely solely on detecting the orientation of the accelerometer with respect to gravity, but rather monitors for a predetermined change in activity level to ascertain whether or not the patient has actually exerted energy to stand up; The fact that a predetermined change in activity level is monitored allows one to discount activity occurring below a certain threshold that might simply be indicative of noise, and account for changes in circadian rhythm (see page 11 of the present specification); There is nothing in the disclosure of Alt that would teach implementing OCT responsive to a monitored predetermined change in activity level; Alt in fact teaches that it is important to understand that *even in the absence of activity*, the device will implement OCT (col. 9, lines 4-10); Such a feat is the result of not relying on patient activity or a predetermined change in patient activity level, but rather relying on accelerometer orientation; Alt further teaches away from implementing OCT responsive to patient activity by stating that in other embodiments the *position sensor* may be used in rate-responsive pacemakers that do *not* rely on activity sensing to detect patient exercise (col. 10, lines 2-8); and

(C). The sensor of Alt performs a dual role; The static positional information is used to control OCT implementation, while the detected activity level is used to control rate-responsive therapy (note the Background of the Invention section of the Alt reference); Rate-responsive therapy and orthostatic compensation therapy are two different issues (note col. 3, lines 17-35 of Alt); Thus the circuit of Alt is not operative to process the monitored patient activity signals to implement OCT;

6. The Office counters with the following argument that it believes supercedes the above points:

The Office agrees that there are clearly differences between Alt and the present invention. However, the limitation, "circuit... being responsive to a predetermined change in activity level to implement an orthostatic compensation therapy" in claim 1, does not appear to distinguish over Alt.

Patentability hinges upon what is meant by "predetermined change in activity level" in claim 1. MPEP 2111 provides guidance for how to interpret claim language and states that during patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification. Additionally, words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. A review of Applicant's specification does not provide a clear definition of "predetermined change in activity level." Page 5, lines 1-4 and 13-15 and page 11, lines 29-31, however, provides one definition for meeting changes in activity level as a device that indicates the patient is standing after a prolonged period of lying. Thus, the specification defines one condition for change in activity level is a change in posture from lying to standing. Additionally, page 5, lines 5-8 and page 8, lines 9-10 and 18-20 state that one type of sensor to measure activity level is an AC accelerometer. An interpretation that a predetermined change in activity level requires Alt's circuitry "to monitor the transition period between two static states" appears to give greater meaning to the claim language than is recited.

Giving claim 1 a reasonable, broad interpretation as described above, column 7, line 42 .column 8, line 64 of Alt discloses the sensor (13) is calibrated to produce predetermined values based on the orientation of the user, including lying and standing, in order for the circuitry to determine when orthostatic therapy is necessary. Column 7, line 13 states the sensor used to measure the activity level is an accelerometer. Furthermore, Alt discloses in column 9, lines 51-57 and Figure 9 that orthostatic compensation therapy is implemented through circuitry responsive to the change in activity level from lying to standing. Thus, despite the issues presented above in sections 5A-5C, the Office considers Alt to anticipate claim 1.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (Pat. No. 5,354,317).

Although Alt does not explicitly refer to the processing circuit 20 and logic circuit 22 as being a microprocessor, the examiner takes Official Notice that such a ubiquitous element would have been an obvious choice by the ordinarily skilled artisan looking to build the device of Alt, due to its recognized suitability for use.

Allowable Subject Matter

9. Claims 9-19 are allowed.

Regarding method claim 9, the steps of monitoring the patient's activity level for a predetermined change in the activity level and pacing at an orthostatic compensation pacing rate if the predetermined change is sensed, is not taught by prior artisans.

Concerning claim 15, the recited means for processing the signals to determine a predetermined change in patient activity level and for implementing an orthostatic compensation therapy based on said change, is not disclosed by prior artisans.

Conclusion


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
April 28, 2004


KENNEDY SCHAEETZLE
PRIMARY EXAMINER